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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,061	06/20/2003	Cesar Z. Lina	VAC.567.1.US	5656

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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,061	LINA ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 25, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding the rejection of claims 1 and 10: Applicant argues that Bowen does not teach or suggest providing a protective cover for a wound" and therefore the prior art references of Brown and Podell do not seek to solve a similar problem in the art. This is not persuasive because both the vacuum pad 40 and manifold 42 covering the pad 40 provide a protective covering for a wound, though they do not meet the limitations of claims 1 and 10. That is the basis for examiner's position that the Bowen and Podell references seek to solve a similar problem in the art. Applicant may find support for examiner's position in any of the figures and Col. 6, lines 44-49 of Bowen.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on August 13, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. It is noted that this IDS was not available to examiner at the time the non-final action was mailed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-6, 9, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowen (U.S. Patent No. 5,827,246) in view of McRae et al (U.S. Patent No. 3, 978,855) and further in view of Podell et al (U.S. Patent No.5,419,913).

With respect to **Claims 1,10:** Bowen teaches a porous pad 40 (Fig. 2) that is permeable to liquids including a porous body 44 having at least a partial outer surface and an inner body. The outer surface (opposite manifold 42 in Fig. 2) is adapted for contact with a surface of a wound and has pores 54 therein of a first average size to enhance biocompatibility, said porous pad 40 to be introduced onto or into a wound so as to be in contact with said wound and with said outer surface adjacent said wound; a vacuum canister 28 for collecting fluids sucked from said wound by a negative pressure source 32 connected to said porous pad 40 through a drainage tube 30.

Bowen does not teach that said pad 40 is secured in or on said wound by a dressing cover for providing a seal around said wound and said porous pad. Podell teaches a surgical drape comprised of a flexible elastomeric material. Since the devices of Bowen and Podell seek to solve a similar problem in the art (i.e. provide a protective cover for a wound) it would be obvious to one of ordinary skill in the art to modify the device of Bowen so as to provide a

dressing cover for said vacuum pad with a reasonable expectation of success. ('246, any figure, Col. 6, lines 44-49; '913, Col. 3, lines 5-7)

The combined teaching of Bowen and Podell does not teach that pad 40 has an outer surface with pores of a first size contacting the wound or an inner body with pores of a second average size that is greater than the pores in the outer surface of said first average size. McRae teaches a wound dressing comprised of open-celled polyurethane foam (Col. 4, lines 53-58) McRae teaches that the polyurethane dressing is compressed to cause cells near at least one surface of said foam to collapse either temporarily or permanently, decreasing their pore size and thus creating a microporous skin on at least that particular surface area, leaving the cells in areas remote from said skin at their original size (now larger compared to the pores at the skin surface). McRae teaches that said first and second pore sizes are to promote sufficient wicking and absorption at the microporous skin surface that is adjacent the wound surface and the larger size is to allow ready absorption while still being small enough to be capable of prohibiting excess exudate absorbed by the microporous skin to pass into the remote region. Therefore it would be obvious to one of ordinary skill in the art to modify the dressing of Bowen to have a vacuum pad comprised of the polyurethane foam taught by McRae having an outer surface with pores of a first average size and an inner body with pores of a second average size greater than said first average size as taught by McRae to promote sufficient wicking and absorption at the outer surface that is adjacent the wound surface and to allow ready absorption while still being small enough to be capable of prohibiting excess exudate absorbed by the microporous skin to pass into the inner body.

With respect to **Claim 2:** The porous pad 40 has an elongated hole to accommodate said drainage tube 30. ('246, Col. 4, lines 22-27, 41-44)

With respect to **Claim 3:** By virtue of having pores in a dressing that are capable of being drained of exudates via negative pressure from a suction pump, the pores of a second average size in the dressing of the combined teaching of Hunt and McRae are considered herein to be vacuum-compatible.

With respect to **Claim 4:** Bowen does not teach either of the materials set forth in claim 4. McRae teaches a pad of polyurethane foam (Col. 5, lines 49-51). The motivation to combine the teachings of Bowen and McRae has been stated *supra* with respect to claim 1.

With respect to **Claim 5:** Hunt does not teach pores having a first size. McRae teaches that pores in the microporous skin area have a diameter in the range of 0.2-200 microns. (Col. 4, lines 42-45, 52-57) McRae teaches that said first and second pore sizes are to promote sufficient wicking and absorption at the microporous skin surface that is adjacent the wound surface and the larger size is to allow ready absorption while still being small enough to be capable of prohibiting excess exudate absorbed by the microporous skin to pass into the remote region. The motivation to combine the teachings of Bowen and Podell and McRae has been stated *supra* with respect to claim 1.

With respect to **Claim 6:** Bowen does not teach a dressing cover made from an elastomeric material. Podell teaches a surgical drape comprised of a flexible elastomeric material. The motivation to combine the devices of Bowen and Podell is stated *supra* with respect to claim 1.

With respect to **Claim 9:** The combined teaching of Bowen and Podell does not teach forming pores by placing said dressing pad in a liquid coating material. McRae teaches a wetting agent (liquid coating material) that an open-celled polyurethane foam is inserted into to a desired amount to achieve a particular pore size. (Col. 6, lines 28-42) The motivation to combine the teachings of Bowen and Podell and McRae has been stated *supra* with respect to claim 1.

With respect to **Claims 12 and 13:** McRae teaches that said microporous skin is formed from the original foam material by compression and not by the addition of another structural entity or chemical compound, therefore the dressing of the combined teaching of Bowen and Podell and McRae is a unitary assembly. The motivation to combine the teachings of Bowen and Podell and McRae has been stated *supra* with respect to claim 1.

With respect to **Claims 14 and 15:** Bowen teaches that the seal around the wound site is substantially airtight via a polyacrylate adhesive ("913, Col. 3, lines 24-26).

With respect to **Claim 16:** Bowen teaches filters interposed either as part of vacuum source 32 or as part of canister 28, therefore Bowen does not teach one filter between said canister 28 and vacuum source 32. However Bowen does teach that air flowing through conduit 30 that connects canister 28 and vacuum source 32 is free of particulate ('246, Col. 5, lines 5-11, 25-29), therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Bowen and Podell and McRae such that one filter is positioned within conduit 30, i.e. between canister 28 and vacuum source 32 with a reasonable expectation of success.

With respect to **Claim 17:** Bowen teaches that a suction pump 32 is adapted to draw liquid from a sealed porous pad 40 through a drainage conduit 30 and into a vacuum canister 28 ('246, Col. 4, lines 22-28).

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowen ('246) in view of McRae et al (U.S. Patent No. 3, 978,855) and further in view of Podell et al (U.S. Patent No.5,419,913) as applied to claims 1-6, 9, 10 and 12-17 above, and further in view of Shioya et al (U.S. Patent No. 4,997,425).

With respect to **Claim 7:** The combined teaching of Bowen and Podell and McRae does not teach the addition of an antimicrobial agent to said wound dressing. Shioya teaches the addition of an antimicrobial agent to the porous wound dressing (Col. 6, line 65-Col. 7, line 2). The benefits of an antimicrobial agent are well known and applicable to devices contacting a wound surface, therefore it would be obvious to someone of ordinary skill in the art to modify the dressing of the combined teaching of Hunt and McRae by adding an antimicrobial agent as taught by Shioya.

6. Claims 8, 11, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowen ('246) in view of McRae et al (U.S. Patent No. 3, 978,855) and further in view of Podell et al (U.S. Patent No.5,419,913) as applied to claims 1-6, 9, 10 and 12-17 above, and further in view of Coffee (U.S. Patent No. 6,252,129)

With respect to **Claims 8 and 11:** The combined teaching of Bowen and Podell and McRae does not teach a foam dressing that may be released from a spray nozzle and deposited directly into the wound cavity, subsequently conforming to the shape of the wound cavity. Coffee teaches spraying a nontoxic polymeric flexible foam deposit into a wound to form a cavity wound dressing, with the dressing conforming to the contours of a cavity wound ('129, Col. 13, lines 52-55). It would be obvious to further modify the wound dressing of the combined teaching of Hunt and McRae to be able to be sprayed directly onto the wound wherein the dressing is a foam material that conforms to the shape of the wound as these spray devices are known, as taught by Coffee ('129, Col. 1, lines 14-17).

With respect to **Claims 18,19:** Coffee teaches that these sprayable substances for treating wounds are known and require a propellant gas to be dispersed onto a substrate, therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Bowen and Podell and McRae so as to provide propellant gas with the nontoxic chemical foam substance as taught by Coffee to ensure the proper application of said substance to the wound to create a properly fitting foam dressing. (Col. 1, lines 13-20)

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761